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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/919,635	07/31/2001	Garry P. Nolan	A-64260-41RMS/AMS	6702

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EXAMINER
WESSENDORF, TERESA D

ART UNIT	PAPER NUMBER
1639	13

DATE MAILED: 02/13/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/919,635	NOLAN ET AL.	
	Examiner	Art Unit	
	T. D. Wessendorf	1639	

-- The MAILING DATE of this communication app ars on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on *26 December 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *26-45* is/are pending in the application.

4a) Of the above claim(s) *39-45* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) *26-38* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *7, 8* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Election/Restrictions

Applicant's election of Group II, claims 23-25 and 46-50, the species, presentation sequence in Paper No. 10 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Status of Claims

Claims 1-22 have been canceled in the Preliminary Amendment of 7/31/01. Claims 23-50 have been added with in said Preliminary Amendment.

Claims 23-25 and 46-50 have been cancelled in the present Amendment of 12/26/02.

Claims 39-45 are withdrawn from consideration as being drawn to non-elected species.

Claims 26-38 are under examination.

Specification

The specification has not been checked to the extent necessary to determine the presence of all possible minor errors (typographical, grammar and etc.). Applicant's cooperation is

requested in correcting any errors of which applicant may become aware in the specification.

Claim Rejections - 35 USC § 112, first paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 26-38 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The specification does not provide an adequate written description of the claimed method wherein the randomized candidate nucleic acids is a target molecule. The specification discloses a method by which the random library is comprised of the bioactive agent and not a target molecule. Likewise, the specification fails to describe a random library with a presentation sequence.

Claim Rejections - 35 USC § 112, second paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 26-38 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A). Claim 26 is incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: the in vitro screening of a molecule that binds a transdominant intracellular bioactive agent. There is no nexus between the preamble and the body of the claim. The preamble recites for in vitro screening for a molecule but the body of the claim does not contain an in vitro step but in vivo step. Also, the preamble recites screening while the body of the claim recites identifying. The process step is confusing as to whether the molecular library of randomized candidate nucleic acids comprises the target molecule. This is inconsistent with what is in the disclosure. The use of different terminologies "a molecule", "molecular

library of randomized candidate nucleic acids" (n.a.) "plurality of randomized peptides" and "a target molecule" to mean the same thing provides for confusion. The metes and bounds of the "different nucleotide sequence"; a "plurality" of cells and "randomized candidate n.a."; "plurality of randomized peptides" and "phenotype of a cell" are not clearly set forth, especially in the absence of positive support in the specification. It is not clear whether the transdominant bioactive agent is the cyclic peptide or not.

B). Claim 27 is indefinite. There is no nexus between the isolating steps and identifying step. Mere isolation of e.g., a cell does not necessarily mean the phenotype of a cell has been identified.

C). Claim 28 does not further limit the base claim. These limitations are already recited in the base claim.

D). Claim 29 is unclear as to the "presentation" sequence that can alter the linear form of a compound to a conformationally restricted form. This broadens the base claim as to an additional component is required for said form.

E). Claim 38 is a duplicate of claim 29 since claim 38 ultimately depends on claim 26.

Double Patenting

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefore ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

Claims 26-38 are rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 1-13 of prior U.S. Patent No. 6,153,380 ('380 Patent) or claims 26 and 29-36 of the instant invention over claims 1 and 8- 15 of the published application 2002/0146710 ('710 published application). This is a double patenting rejection.

The instant claimed method is identical to the claims of the '380 Patent. The instant method recites exactly the same process steps as the '380 Patent or the '710 published application.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless -
>
> (e) the invention was described in-
> (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effect under this subsection of a national application published under section 122(b) only if the international application designating the United States was published under Article 21(2)(a) of such treaty in the English language; or
> (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that a patent shall not be deemed filed in the United States for the purposes of this subsection based on the filing of an international application filed under the treaty defined in section 351(a).

Claims 26-28, 30-31 are rejected under 35 U.S.C. 102(e) as being anticipated by Jensen et al (2001/0053523).

Jensen at page 1, paragraph [0013] discloses a method comprising (a) production of a pool of appropriate vectors each containing totally or partly random DNA sequences, (b) efficient transduction of said vectors into a number of identical, e.g. mammalian, cells in such a way that a single ribonucleic acid and possibly peptide is expressed or a limited number of different random ribonucleic acids and peptides are expressed by each cell, (c) screening of said transduced cells to see whether some of them have changed a certain phenotypic

trait,(d) selection and cloning of said changed cells, (e) isolation and sequencing of the vector DNA in said phenotypically changed cells, and (f) deducing the RNA and peptide sequences from the DNA sequence. See further the Examples at pages 3-5 which presents the detailed description using specific components in the methods. Therefore, the specific method steps of Jensen fully meet the broadly claimed method.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 23-38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jensen in view of either Luzzago (Gene) or Dower et al (WO 91/19818).

Jensen is discussed, above. Jensen does not disclose a presentation sequence. Luzzago discloses at page 52, col. 2, a method of identifying a peptide comprising constructing a cyclic peptide library. See further the expressed cyclic peptide at

Table 1, page 53 and col. 2. Dower discloses at page 6, lines 10-23 a method of identifying a peptide comprising constructing a cyclic peptide library. See further page 9, lines 25-29 as to the size of the library of the n.a. used; page 14, line33 up to page 15, line 5 as to the cys residue containing peptide and page 19, line 35 up to page 22, line 16 as to the conformational constraints imposed on the peptide (presentation structure as claimed) and the phenotype effect of the library on the cell at page 23, line 30 up to page 25, line 23. It would have been obvious to one having ordinary skill in the art at the time the invention was made to include a presentation sequence in the method of Jensen, in the manner as taught by Luzzago or Dower. Each of the Luzzago and Dower references discloses the conventionality of a method wherein a library contains a presentation sequence. One having ordinary skill in the art would include said presentation sequence, if one desires a conformational form of an expressed linear product. Because of the stability conferred by a presentation sequence relative to a linear sequence, one would be motivated to use a presentation sequence. Such stable conformation provides for compounds that lead to pharmaceutical drugs stable in vivo.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Kamb discloses a method for identifying n.a. sequences encoding agents that affect cell phenotypes.

Huffman discloses a library of cyclic peptide.

No claim is allowed.

[None of the references cited by the Examiner is included herein. The copies have been provided to applicants in the copending application, 09/918,601].

Any inquiry concerning this communication or earlier communications from the examiner should be directed to T. D. Wessendorf whose telephone number is (703) 308-3967. The examiner can normally be reached on Flexitime.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on (703) 306-3217. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-7924 for regular communications and (703) 308-7924 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

T. D. Wessendorf
Primary Examiner
Art Unit 1627

tdw
2/10/03